UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**CASE NO. 1:14-CV-01748** **MDL 2545** **JUDGE MATTHEW F. KENNELLY** **This Document Relates to:** ***Mitchell* v. *AbbVie*,** **Case No. 1:14-cv-09178**

DEFENDANTS' MOTION AND SUPPORTING MEMORANDUM FOR JUDGMENT AS A MATTER OF LAW PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 50(a)

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The Court should enter judgment for Defendants AbbVie Inc. and Abbott Laboratories (collectively, "AbbVie") because no reasonable jury could find for Plaintiff on his three claims. *See* Fed. R. Civ. P. 50(a). *First*, all three fail because Plaintiff's causation expert, Dr. Ardehali, conceded that Plaintiff had numerous risk factors that completely explained his heart attack. *Second*, his strict liability and negligence warning claims fail because he did not demonstrate the "reasonable evidence of a causal association" required to add a warning without prior Food and Drug Administration (FDA) approval; he did not prove that it was unreasonable not to include additional cardiovascular (CV) warnings; and his prescriber, Dr. Canzler, expressly warned him of potential CV risk. *Third*, the strict liability claim fails because Plaintiff did not introduce evidence of consumer expectations. *Fourth*, Plaintiff's misrepresentation claim fails because he did not prove any false statements, let alone any reliance; the claim rests on inherently contradictory testimony; and Plaintiff admitted that he did not rely on any AbbVie ads in deciding to use AndroGel, while Dr. Canzler admitted that he independently assessed the benefits and risks of AndroGel and relied solely on his medical judgment and experience in making his prescribing decision and continues to prescribe AndroGel today even after Plaintiff's heart attack and reports of potential CV risks in 2014. *Finally*, the Court should strike Plaintiff's punitive damages request due to the absence of any nexus between Plaintiff's AndroGel treatment and the supposed punitive conduct identified by Plaintiff's counsel.

ARGUMENT

I. PLAINTIFF DID NOT OFFER SUFFICIENT EVIDENCE THAT ANDROGEL WAS A BUT-FOR CAUSE OF HIS HEART ATTACK

Each of Plaintiff's claims required him to prove that AbbVie caused his heart attack. Tr. 152:13–19, attached hereto as Exhibit A. To satisfy this burden under Oregon law, Plaintiff had to demonstrate that the heart attack "would not have occurred but for AbbVie's conduct." Ex. A

at 152:18–19; *see Joshi* v. *Providence Health Sys. of Or. Corp.*, 149 P.3d 1164, 1169 (Or. 2006). Dr. Ardehali therefore needed to rule out the possibility of Plaintiff having the heart attack without AndroGel. Ex. A at 152:20–22; *Joshi*, 149 P.3d at 1169 ("[T]he defendant's conduct is not a cause of the event, if the event would have occurred without it.").

Dr. Ardehali's opinion did not meet this standard. To the contrary, Dr. Ardehali conceded that Plaintiff suffered from many risk factors that alone sufficed to cause his heart attack. Ex. A at 1445:7–1447:3, 1449:21–1450:9, 1451:6–1453:4, 1454:9–14. At the time of his heart attack, Plaintiff undisputedly had several cardiac risk factors, including a 34-year history of smoking, hypertension, hyperlipidemia, obesity, a family history of heart disease, and lack of exercise. Ex. A at 1449:21–1450:9, 1451:6–1453:4. Dr. Ardehali agreed that without AndroGel, Plaintiff's risk factors gave him a 15–18% 10-year risk estimate for having a heart attack—at least double what Dr. Ardehali considers "high risk." Ex. A at 1463:15–19, 1469:1–12.

Significantly, Dr. Ardehali would have told Plaintiff between 2010 and 2012 that he was at risk of a heart attack "any day" due to those factors. Ex. A at 1459:1–11, 1459:24–1460:2. Dr. Ardehali further admitted that there was nothing unusual about Plaintiff's heart attack in his hospital records to suggest a cause besides his risk factors; to the contrary, those records identified the same cardiac risk factors. Ex. A at 1460:24–1462:9. Plaintiff therefore failed to satisfy the requirement under Oregon law of demonstrating that he would have avoided his heart attack had he not used AndroGel. Because Plaintiff produced insufficient evidence on the core causation element, the Court should enter judgment for AbbVie on all claims.

II. PLAINTIFF DID NOT OFFER SUFFICIENT EVIDENCE OF INADEQUATE WARNINGS TO SUPPORT STRICT LIABILITY AND NEGLIGENCE

Plaintiff's strict liability and negligence claims fail for the independent reason that AndroGel's labeling included adequate warnings, as measured by the "scientific knowledge that

was reasonably available at the time" of Plaintiff's prescription. Ex. A at 149:7–17, 150:19–151:5; *see McEwen* v. *Ortho Pharm. Corp.*, 528 P.2d 522, 528–29 (Or. 1974).

Plaintiff's claims in this case "are not claims for violation of FDA regulations." Ex. A at 153:25–154:1. Rather, Plaintiff's strict liability and negligence claims required him to prove that AbbVie gave unreasonable warnings for purposes of Oregon law. *See* Ex. A at 149:7–9, 150:20–22. Plaintiff had to establish that reasonable evidence of a causal association existed before Plaintiff's heart attack and that AbbVie unreasonably did not provide additional CV warnings based on the state of science at the time Plaintiff used AndroGel.

Plaintiff failed to offer this proof. *First*, Plaintiff did not show that AbbVie lawfully could have added CV warnings. To satisfy this requirement, Plaintiff had to meet the FDA standard prohibiting additional warnings absent "reasonable evidence of a causal association." 21 C.F.R. § 201.57(c)(6)(i). AbbVie could only use the "changes being effected" (CBE) process to bypass prior FDA approval and add "newly acquired" safety information if it established such reasonable evidence of a causal association. *See* 21 C.F.R. § 314.70(c)(6)(iii). Under FDA Guidance, an adverse event "safety signal," standing alone, does not meet this standard. *See* Ex. 3094.7; *see also Matrixx Initiatives, Inc.* v. *Siracusano*, 563 U.S. 27, 44 (2011) ("[T]he mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events[.]"). Nor was there even a "safety signal" under FDA Guidance given Dr. Ardehali's admission that the heart attack incidence rate did not exceed the background rate. Ex. A at 1507:9–15. Without meeting this standard, federal law preempts Plaintiff's state-law warning claims. *See Utts* v. *Bristol-Myers Co.*, 251 F. Supp. 3d 644, 661 (S.D.N.Y. 2017) (to avoid preemption, "the plaintiff must show that there existed 'newly acquired information' such that the defendants could unilaterally change the label pursuant to the

CBE regulation without FDA approval"). No reasonable jury could conclude that Plaintiff met his burden where the FDA itself, even today, has found no reasonable evidence of a causal association based on the same evidence that Plaintiff now points to.

Second, Plaintiff failed to demonstrate that AbbVie gave unreasonable warnings under Oregon law. None of Plaintiff's experts offered such an opinion, and without this proof, the jury cannot reasonably find the AndroGel warnings inadequate for purposes of the warning claims.

Third, Plaintiff's warning claims fail because his prescribing physician expressly warned him about a potential heart attack risk, and still prescribes AndroGel today, even after Plaintiff's heart attack and reports of possible CV risk in 2014.

A. Plaintiff Failed to Demonstrate Reasonable Evidence of a Causal Association

1. Dr. Ardehali's Flawed Adverse Event Analysis Was Insufficient to Establish Reasonable Evidence of a Causal Association in 2007

Dr. Ardehali testified that adverse event reports, one small clinical trial, and one meta-analysis that reported non-statistically significant imbalances in CV events provided "reasonable evidence of a causal association" as of 2007. Ex. A at 1373:22–1374:1, 1384:22–1385:15. However, Dr. Ardehali simply disagreed with the FDA's findings to the contrary; he did not provide a sufficient factual basis for the FDA to have permitted or required a labeling change prior to Plaintiff's AndroGel use. Ex. A at 1372:9–18, 1492:16–19, 1516:20–24. Dr. Ardehali received the adverse event reports from counsel and did not independently review AbbVie's adverse event database, let alone assess such reports in context of the number of AndroGel users and/or the incidence of heart attacks in the general population. Ex. A at 1499:14–1500:12. He also acknowledged that the adverse event reports went to the FDA. Ex. A at 1496:17–1497:1.

Dr. Ardehali conceded that the FDA has never, even today, found reasonable evidence of a causal association based on these reports. Ex. A at 1521:18–20. And Dr. Pence agreed that

"the FDA never thought there should be a warning [about CV risk] prior to 2015." Ex. A at 1890:6–24. Both experts likewise acknowledged that the FDA expressly found in a 2010 review that the studies "do not support an association between [testosterone replacement therapy (TRT)] and an increased risk of cardiovascular events in men." Ex. A at 1516:5–8, 1894:18–1895:1. In addition, Dr. Pence conceded that, in 2010, the FDA reviewed a number of studies and found that "one cannot make the conclusion based on these studies that testosterone therapy increases the risk of cardiovascular disease." Ex. A at 1896:23–1897:2. Moreover, Plaintiff's experts agreed that "the FDA never mandated a warning or mandated additional testing prior to and through the time Mr. Mitchell had a heart attack." Ex. A at 1516:9–19, 1901:18–21.

Dr. Pence also acknowledged that "the FDA would not draw conclusions about drug event causality from post-marketing spontaneous reports for CV events with testosterone use." Ex. A at 1882:25–1883:4; Ex. 3258.65. And Dr. Ardehali conceded that even by 2014—two years after Plaintiff's heart attack—the FDA Advisory Committee did not find reasonable evidence of a causal association. Ex. A at 1517:23–1520:6. The mere "weak signal for possible risk" identified then does not suffice as a matter of law to permit a label change. *See* Ex. 3094.7; *Utts*, 251 F. Supp. 3d at 670 (holding state-law claims preempted despite FDA identifying "a potential signal of a 'serious risk/new safety information'" based on adverse event reports). Thus, the adverse event reports through 2007 and two studies relied on by Dr. Ardehali do not constitute the "reasonable evidence of a causal association" necessary to avoid preemption.

2. The Basaria Study Was Not Reasonable Evidence of a Causal Association

The 2010 Basaria study also does not provide reasonable evidence of a causal association to support a label change. No expert offered a contrary opinion. Dr. Ardehali and Dr. Pence both conceded that the FDA did not find reasonable evidence of a causal association after

reviewing this study. Ex. A at 1515:4–1516:12, 1896:2–1897:11. Moreover, the FDA undisputedly found limitations with the Basaria study. Ex. A at 1519:15–20. Given these concessions, the Basaria study could not have required or permitted an additional warning.[1]

B. Plaintiff Did Not Prove Inadequate Warnings Under State Law

Plaintiff also has not presented evidence that AbbVie's CV warning was unreasonable as a matter of Oregon law. *See* Ex. A at 1878:23–25 (Dr. Pence opining that AbbVie should have added a warning by 2007 merely "because there was reasonable evidence of a causal association" with CV events). A claim that AbbVie did not comply with the FDA regulation requiring reasonable evidence of a causal association to change the label does not mean that the warnings were unreasonable as a matter of state law. Indeed, Plaintiff (and this Court) have expressly rejected the suggestion that his state-law claims are really an impermissible attempt to privately enforce the Food, Drug, and Cosmetic Act, which contains no private right of action. Ex. A at 153:25–154:1; *see Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Given the absence of any proof that AbbVie failed to satisfy Oregon's state-law standard, the Court should enter judgment for AbbVie on Plaintiff's warning claims.

C. Plaintiff's Warning Claims Also Fail Because His Prescribing Physician Expressly Warned Him of a Potential Heart Attack Risk

Plaintiff's physician, Dr. Canzler, gave a "standard warning and clarification" to Plaintiff and other hypogonadal patients before prescribing AndroGel. Ex. A at 1736:10–23. Dr. Canzler "specifically told them that there were risks for heart attacks." Ex. A at 1736:17–18. Moreover, when asked about potential risks that he discussed with Plaintiff, Dr. Canzler confirmed, "I know

[1] Although it is unclear whether Plaintiff advances a warning claim that AbbVie failed to clarify the AndroGel indication, such a claim would likewise fail. No expert opined that federal law required or permitted such a change. To the contrary, the evidence established that the FDA considered and rejected narrowing the indication in 2007, Ex. A at 898:18–899:1, and permitted AbbVie to change the AndroGel 1.62% and 1% indications sections in 2012 to include the phrase "such as" when listing examples of conditions causing primary hypogonadism. Ex. A at 901:7–24; Exs. 3214.3, 3215.3. Nor did Plaintiff present any "newly acquired" information during the 2007–2012 time frame that would have supported such a change.

we spoke of heart problems." Ex. A at 1744:15–16. Thus, Dr. Canzler knew and appreciated the potential risks, and expressly warned Plaintiff. Furthermore, Dr. Canzler prescribed AndroGel based on his independent medical judgment, not anything that AbbVie said. Ex. A at 1761:22–25, 1764:22–1765:3. An additional warning therefore would not have changed Dr. Canzler's prescribing decision. Indeed, he specifically testified that he exercised his medical judgment to determine that the benefits outweighed the risks for Plaintiff and that he still prescribes AndroGel today, even after Plaintiff's heart attack and reports of possible CV risk in 2014. Ex. A at 1725:8–11, 21–25, 1735:19–20, 1744:10–1745:1, 1745:15–18. Dr. Canzler's express warning and his reliance on his own medical judgment both sever any causal link between the allegedly inadequate warning and Plaintiff's injury. *See Vaughn* v. *G.D. Searle & Co.*, 536 P.2d 1247, 1250–51 (Or. 1975) (en banc). Thus, the jury could not reasonably find a failure to warn that caused Plaintiff's injury.

III. PLAINTIFF'S STRICT LIABILITY CLAIM ALSO FAILS BECAUSE HE DID NOT PRODUCE EVIDENCE THAT ANDROGEL WAS DEFECTIVE OR UNREASONABLY DANGEROUS

Plaintiff's strict liability claim required proof that AndroGel was "in a defective condition that was unreasonably dangerous." Ex. A at 148:18–19. In addition to the foregoing failures of proof on causation and the inadequacy of warnings, this claim fails because Plaintiff has not satisfied this standard. He presented no evidence of any design defect, relying exclusively on an alleged warnings defect. However, Plaintiff cannot establish any such defect because he has not produced evidence that "is sufficient for the jury to make an informed decision about what ordinary consumers expect[ed]" with respect to AndroGel. *McCathern* v. *Toyota Motor Corp.*, 23 P.3d 320, 331 (Or. 2001). Plaintiff's own expectations would not meet this standard, but if they did, Plaintiff offered no evidence as to those expectations. Indeed, he conceded that he knew nothing about AndroGel before Dr. Canzler prescribed it for him. Ex. A at 1693:16–18.

Moreover, to the extent that this standard considers Dr. Canzler's expectations, the evidence shows that Dr. Canzler believed, at the time he initially prescribed AndroGel to Plaintiff, that AndroGel was a safe product for him to use. Ex. A at 1745:15–18. To this day, Dr. Canzler still believes that AndroGel is a good medication, Ex. A at 1740:8–10, and his patients have done well on AndroGel over time and have reported quick improvements in their symptoms after using AndroGel, Ex. A at 1734:10–1735:5. Moreover, Dr. Canzler testified that he has not had any reports from patients of adverse events experienced on TRT, and he still prescribes AndroGel today. Ex. A at 1735:16–20.

IV. THE MISREPRESENTATION CLAIM FAILS BECAUSE THERE IS NO CLEAR AND CONVINCING EVIDENCE THAT PLAINTIFF OR HIS PRESCRIBING PHYSICIAN SAW OR RELIED ON ANY FALSE REPRESENTATION

Plaintiff had to prove each element of his fraudulent misrepresentation claim by "clear and convincing evidence." Ex. A at 151:16–19. He failed to do so because (i) he did not demonstrate any false representation, (ii) his marketing expert, Dr. Kessler, rested his opinion on FDA regulations but offered no opinion that AbbVie violated any of those regulations, and (iii) Plaintiff did not show that he or his prescriber saw or relied on any false representation.

A. No Reasonable Jury Could Find that AbbVie Made a False Representation

Plaintiff had to prove by clear and convincing evidence that AbbVie made a "material misrepresentation that was *false*." *Strawn* v. *Farmers Ins. Co. of Or.*, 258 P.3d 1199, 1209 (Or. 2011) (emphasis added); *see Oksenholt* v. *Lederle Labs.*, 656 P.2d 293, 299 (Or. 1982) ("Misrepresentation requires a false representation[.]"); Ex. A at 151:20–21 (instructing that Plaintiff's misrepresentation claim required clear and convincing proof of a "false representation regarding a material matter"). As these cases demonstrate, Oregon law imposes a "falsity" standard; allegations of "misleading" or "confusing" statements do not suffice.

Dr. Kessler's opinion fails to satisfy this "falsity" standard. While he purported to offer a general opinion that the marketing and promotion of AndroGel was "false and misleading," Ex. A at 797:20–798:11, he did not identify a single "false" statement in any AndroGel ad, let alone an ad that Plaintiff or his doctor saw. To the contrary, Dr. Kessler expressly conceded that the FDA has never found any AndroGel ads that ran, whether branded or unbranded, to be false or misleading, despite having reviewed and commented upon several of these ads "frame by frame," "line by line." Ex. A at 878:19–879:4; 834:9–10, 17–19; 836:12–25; 843:25–844:3. He also identified no instance where the FDA told AbbVie that it was marketing off-label or "over-promoting." Ex. A at 872:9–874:2. Plaintiff has presented no claim or evidence that AbbVie failed to follow any specific FDA directive to change or discontinue its ads.

Plaintiff cannot save this claim by arguing that the FDA did not act due to a lack of jurisdiction to review unbranded ads. Indeed, while Dr. Kessler asserted that AndroGel's unbranded ads improperly implied benefits and were improperly linked to branded ads, he conceded that the FDA has jurisdiction over unbranded ads that imply benefits or are so linked. Ex. A at 864:24–865:15. Thus, by Dr. Kessler's own testimony, the FDA had jurisdiction to review these unbranded ads if they did in fact improperly imply benefits or link to branded ads, and its inaction with respect to them is telling. Further, although Dr. Kessler claimed that unbranded ads were improper because they discussed signs and symptoms of low testosterone without FDA approval, he conceded that branded, FDA-approved ads also discussed signs and symptoms of lower testosterone. Ex. A at 846:10–20. He also conceded that these same signs and symptoms were listed in the AndroGel 1% label until 2015. Ex. A at 860:8–12, 977:6–9.

Nor has Plaintiff produced sufficient evidence of fraud based on his new theory that AbbVie fraudulently concealed AndroGel's lack of demonstrated safety and efficacy outside its

indication.[2] This concealment theory requires proof of "active concealment," as distinct from a "simple nondisclosure." *Paul* v. *Kelley*, 599 P.2d 1236, 1238 (Or. Ct. App. 1979); *see In re Conduct of Brown*, 956 P.2d 188, 196 (Or. 1998). Yet Plaintiff pointed to no affirmative conduct by AbbVie to actively conceal any lack of safety or efficacy outside the indication.

In the absence of such active concealment, Plaintiff could only establish fraud based on nondisclosure if AbbVie possessed an affirmative "duty to disclose." *State Const. Corp.* v. *Scoggins*, 485 P.2d 391, 393 (Or. 1971) (en banc) ("A failure to disclose facts . . . amounts to fraud only where there is a duty to disclose."); *Gebrayel* v. *Transamerica Title Ins. Co.*, 888 P.2d 83, 89 (Or. Ct. App. 1995) ("For non-disclosure to form the basis of a fraud claim, defendant must be under a duty to disclose."). But AbbVie bore no such duty to disclose any lack of demonstrated safety and efficacy outside AndroGel's FDA-approved indication.

To recognize an affirmative duty to disclose under these circumstances would turn standard market transactions on their head. *See Paulsell* v. *Cohen*, No. CIV-00-1175-ST, 2002 WL 31496397, at *24 (D. Or. May 22, 2002) ("[P]arties to an impersonal market transaction owe no duty of disclosure to one another absent a fiduciary or agency relationship, prior dealings, or circumstances such that one party has placed trust and confidence in the other." (quoting *Paracor Fin., Inc.* v. *Gen. Elec. Capital Corp.*, 96 F.3d 1151, 1157 (9th Cir. 1996))); *see also, e.g.*, *Gebrayel*, 888 P.2d at 89 (absent special circumstances, "a duty to disclose cannot be

[2] AbbVie maintains that Plaintiff waived this fraudulent concealment claim by failing to pursue it at the first trial. *See Cont'l T.V., Inc.* v. *G.T.E. Sylvania Inc.*, 694 F.2d 1132, 1136 n.6 (9th Cir. 1982) (holding that plaintiff could not rely on new allegations during retrial where it "made no such allegations in its original case"); *PSKS, Inc.* v. *Leegin Creative Leather Prods., Inc.*, No. CV 2:03 CV 107(TJW), 2009 WL 938561, at *6 (E.D. Tex. Apr. 6, 2009) ("[N]othing prevented [plaintiff] from raising its horizontal agreement and conspiracy allegations in the original trial, and it cannot do so now."), *aff'd*, 615 F.3d 412 (5th Cir. 2010); *Span-Deck, Inc.* v. *Fabcon, Inc.*, 570 F. Supp. 81, 91 (D. Minn. 1983) (holding that plaintiff waived certain claims on retrial by "not assert[ing] these claims in the original trial or on appeal"); *cf. Huff* v. *Dobbins, Fraker, Tennant, Joy & Perlstein*, 243 F.3d 1086, 1090 n.5 (7th Cir. 2001) (holding that plaintiff could not raise on second appeal issue that she did not raise on first appeal).

imposed"); *Salvas* v. *McEuen*, 704 P.2d 1166, 1168 (Or. Ct. App. 1985) (property sellers generally have no duty to disclose that land is not suitable for the buyer's intended purpose).

Moreover, Plaintiff cannot support a concealment claim given that he and his prescriber both received the AndroGel labeling, setting forth the indication for which the FDA had approved AndroGel as safe and effective, as well as the relevant scientific data. Ex. 640i; *see Salvas*, 704 P.2d at 1168 (rejecting claim of fraud based on nondisclosure where plaintiff had "an adequate opportunity" to discover the undisclosed fact himself); *Paulsell*, 2002 WL 31496397, at *26 (same with respect to counterclaim). As Dr. Kessler conceded, prescribing physicians would receive the labeling, which he referred to as "the holy grail" of information about the drug. Ex. A at 710:6–17, 881:22–882:20. And Plaintiff admitted that he likewise received the AndroGel label including the medication guide every time that he filled his prescription. Ex. A at 1692:21–25. Moreover, Dr. Canzler never diagnosed the cause of Plaintiff's hypogonadism, meaning that it was "idiopathic" and therefore within the labeled indication. Ex. A at 538:9–11, 1787:6–9.

Given Plaintiff's failure to demonstrate any false statement, active concealment, or nondisclosure in the face of a duty to disclose, the Court should enter judgment for AbbVie on Plaintiff's fraudulent misrepresentation claim.

B. No Reasonable Jury Could Credit Dr. Kessler's Inherently Contradictory Testimony

Additionally, Plaintiff's misrepresentation claim rests on inherently inconsistent testimony from Dr. Kessler, further demonstrating Plaintiff's inability to prove this claim by clear and convincing evidence.

Dr. Kessler testified that AndroGel's ads were "false and misleading" because the Company marketed and promoted AndroGel outside of the drug's indication. Ex. A at 798:3–7. However, this opinion rests on matters that Dr. Kessler readily admitted are governed by FDA

regulations, including the intended use of AndroGel, Ex. A at 821:14–21, and what AndroGel can be promoted for, Ex. A at 821:25–822:2. Dr. Kessler further opined on whether AndroGel's branded and unbranded ads were improperly linked—something that is only potentially unlawful under FDA regulations. *See* FDA, *Guidance for Industry: "Help-Seeking" Other Disease Awareness Communications by or on Behalf of Drug and Device Firms* 5–7 (2004).

Yet, at the same time, Dr. Kessler testified that he is *not* offering an opinion on whether any actions by AbbVie violated FDA law or regulations. Ex. A at 825:16–18. No reasonable jury could reconcile these contradictory opinions upon which Plaintiff relies to prove his fraudulent misrepresentation claim. Moreover, to the extent that Dr. Kessler's opinion rests on FDA regulations, Plaintiff's reliance on that opinion violates *Buckman*. *See* 531 U.S. at 353.

C. There Is No Evidence that Plaintiff or His Prescribing Physician Saw or Relied on Any False Representation

Plaintiff also failed to prove by clear and convincing evidence that he or his prescriber saw and relied on any false representation when deciding to use or prescribe AndroGel. Ex. A at 152:8–9.[3] Indeed, Plaintiff admitted that he did not start using AndroGel because of any AbbVie ads. Ex. A at 1693:19–23. Plaintiff further conceded that he never heard of low testosterone or AndroGel before Dr. Canzler diagnosed him and prescribed it for him. Ex. A at 1661:12–14, 1693:16–18. He did not recall seeing any advertisement for AndroGel or any other particular brand of TRT or low testosterone generally, but believes that he saw disease awareness ads about low testosterone after he began using AndroGel. Ex. A at 1666:14–22, 1693:12–15. Nor did Plaintiff recall Dr. Canzler ever giving him any questionnaire (such as ADAM) or ever visiting the IsItLowT.com website, Ex. A at 1693:24–1694:10, and Dr. Canzler confirmed that he did not use the ADAM questionnaire with Plaintiff, Ex. A at 1790:17–19. Moreover, Plaintiff relied not

[3] AbbVie preserves its argument that the Court should have instructed the jury that the misrepresentation claim required proof of reliance by both Plaintiff and his prescriber. *See Mitchell* ECF 146 at 2.

on any statement by AbbVie in advertisements or the label, but on Dr. Canzler's judgment in deciding to use AndroGel. Ex. A at 1692:21–1693:8. Finally, Plaintiff did not recall reading any materials that came with his AndroGel prescriptions. Ex. A at 1692:21–1693:2. Thus, no reasonable jury could conclude that Plaintiff relied on any false representation by AbbVie.

Similarly, the evidence establishes that Dr. Canzler's treatment decisions for Plaintiff rested on his training, experience, and medical judgment, rather than on anything AbbVie said. Ex. A at 1764:22–1765:3. Dr. Canzler received marketing from TRT manufacturers but could not recall any medical articles that sales representatives left behind, and he independently stayed abreast of medical developments. Ex. A at 1760:2–4, 17–20. Furthermore, he made independent prescribing decisions based on his medical judgment, notwithstanding any marketing. Ex. A at 1761:18–25. Dr. Canzler never "committed" to using a medication at a sales representative's behest, Ex. A at 1774:15–17, and he did not do anything in his practice simply because a representative told him to do so, Ex. A at 1791:18–22. Although Dr. Canzler acknowledged that advertising sometimes influenced men to ask about low testosterone or for TRT, there is no evidence that that occurred in this case. Ex. A at 1772:23–1773:6.

Dr. Canzler's testimony likewise established that he was not confused or misled about the scope of AndroGel's indication, even under Plaintiff's theory of the case. He reportedly understood "age-related" hypogonadism to be outside the indication and did not recall any representative telling him that he should prescribe AndroGel for that condition. Ex. A at 1787:14–16, 21–24. In any event, Plaintiff's theory of "age-related" fraud has no bearing on this case where Dr. Canzler never diagnosed Plaintiff with "age-related" hypogonadism. Ex. A at 1786:21–1787:5. Indeed, Plaintiff was only 43, with unequivocally low testosterone, at the time of his first prescription. Ex. A at 1743:23–1744:6. Finally, any suggestion that Dr. Canzler was

somehow deceived or misled by AbbVie's risk information is belied by the fact that he warned Plaintiff of the potential CV risks. Ex. A at 1736:10–20.

V. OREGON LAW AND DUE PROCESS BAR ANY PUNITIVE DAMAGES

The Court should enter judgment for AbbVie with respect to punitive damages. *First*, AbbVie respectfully maintains that the Court should apply Oregon punitive damages law to the claims of an Oregon man who used AndroGel and had his heart attack in Oregon. *See Townsend* v. *Sears, Roebuck, & Co.*, 879 N.E.2d 893, 908–09 (Ill. 2007). Under Oregon law, a drug manufacturer "shall not be liable for punitive damages" where the drug either (i) "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration," or (ii) "[i]s generally recognized as safe and effective" by the FDA. O.R.S. § 30.927(1)(a)–(b). There is no dispute that ever since AndroGel's initial approval in 2000, it has remained approved as safe and effective by the FDA, and has been accompanied by FDA-approved labeling.[4] Allowing punitive damages here would violate due process given that Oregon, where Plaintiff resides and had his heart attack, would not permit such damages. *Cf. BMW of N. Am., Inc.* v. *Gore*, 517 U.S. 559, 572–75 (1996).

Second, even applying Illinois punitive damages law, Plaintiff has not shown that AbbVie's conduct reflects either "an actual or deliberate intention to harm" or an "utter indifference to or conscious disregard for the safety of others." Ex. A at 155:9–11. Plaintiff has identified no evidence that AbbVie intended to cause harm or consciously disregarded consumer

[4] Plaintiff cannot satisfy the limited statutory exception that arises where the plaintiff has proven by clear and convincing evidence that the defendant "knowingly in violation of applicable federal [FDA] regulations withheld from or misrepresented to the agency or prescribing physician information known to be material and relevant to the harm which the plaintiff allegedly suffered." O.R.S. § 30.927(2). Plaintiff has not advanced any preempted claim that AbbVie violated FDA regulations or withheld information from the FDA. And as noted above, Plaintiff has presented no evidence, much less clear and convincing evidence, that AbbVie made misrepresentations or withheld information from Dr. Canzler.

safety. Plaintiff's counsel promised a punitive damages case premised on allegations of long-standing "off-label" promotion for "age-related hypogonadism." ECF 1962 at 3–5. But counsel did not link any of these allegations or evidence to Plaintiff. No advertising influenced Plaintiff's decision to use AndroGel. *See supra* at Section IV.C. Dr. Canzler did not determine that Plaintiff suffered from "age-related hypogonadism" and, regardless, understood that the product was not approved for such condition. *Id.* When prescribing a medication to a patient, Dr. Canzler made his own independent decisions based on his medical judgment. Ex. A at 1725:21–25. And, with respect to Plaintiff in particular, Dr. Canzler testified that he made his decision based on his own experience with the medication, not because of something any sales representative told him. Ex. A at 1764:22–1765:3.

Given the absence of any link between the supposed punitive damages evidence and the facts relevant to Plaintiff's care and treatment, permitting a punitive damages award in this case would violate due process. As the Supreme Court has cautioned: "A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business. Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis." *State Farm Mut. Auto Ins.* v. *Campbell*, 538 U.S. 408, 422–23 (2003); *see Philip Morris USA* v. *Williams*, 549 U.S. 346, 353–58 (2007) (due process bars punitive damages to punish for harm caused to others).

CONCLUSION

For the foregoing reasons, the Court should enter judgment in AbbVie's favor on all of Plaintiff's claims.

Dated: March 21, 2018

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CERTIFICATE OF SERVICE

I, David Bernick, hereby certify that on March 21, 2018, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ David Bernick
David Bernick